

**IAP5 Rec'd PCT/PTO 29 SEP 2006**URINARY INCONTINENCE DEVICE

The present invention relates to a female incontinence device, in particular an external incontinence device.

5 Due to the anatomy of the female external urogenital organs, the management of incontinence in female patients has always been difficult both in terms of preventing leakage and acceptability for the patient. There have been a number of devices for female incontinence that attempt to secure an effective seal in a number of ways. Some devices provide an intra vaginal structure to support the device in place.

10 Examples of such devices include those described in US patent 3776235 (Ratcliffe et al), US 3661155 (Linden), US 4198979 (Cooney et al), US 4019498 (Hawtrey et al), US 5785640 (Keresch et al) and UK patent applications GB 2126902A and GB 2090144A. However, such devices have been found to be rigid, uncomfortable, intrusive and still prone to leakage.

15 Other devices have used an external adhesive in an attempt to seal the device to the patient's skin and avoid leakage. Examples of such devices include US patent 4822347 (MacDougal) and UK applications GB 2129686A and GB 2193438A. These devices have also proven to be ineffective in providing an effective seal,

20 particularly with mobile patients.

Further devices include US 4846819 (Welch) which employs a deformable polymer gel ring to provide a seal. The use of a sealing pad of foam plastic material is described in US patent 3374790 (Mayhorne) but again these devices have been found

25 to be ineffective in preventing leakage.

Other devices provide a contact seal with the patient between the labia minora and labia majora. These devices include US4889533 (Beecher) which includes a pessary for insertion into the vagina to keep the device in place, an elevated side wall around the labia minora and flanges that engage the labia majora. The device requires a flexible crotch panel that is attached to a waistband through straps. Such a device is uncomfortable due to vaginal insertion and engagement of the labia majora.

US3995329 (Williams) describes a hand held urine collection device for use in a standing position designed to be held and pressed against labia majora and has

10 elevated side walls of limited resilience such that when hand pressure is applied by the user the flesh in contact causes abutted flesh to yield to conform to the device to form a seal. The device is not designed for continuous wear and is not suitable for incontinent patients. US5893176 (Magiera et al) describes a hand held device for urine collection whilst in the standing position, the device includes two sealing rings,

15 the interior ring comprises a circumferential wall which engages the exterior of the labia minor and a exterior ring which engages the exterior of the labia majora. The device is intended to be hand held to allow a female user to urinate in a standing position and is not suitable for use in an incontinent person. Such devices include an elevated ring structure to engage the labia minora and an exterior wall or flanges to engage and press on the labia majora to keep the device in place and obtain a contact

20 seal. However, it is found that pressing against the exterior of the labia majora to make a seal is uncomfortable and restrict patient movement and for an active patient such devices are prone to move and rub the patient's skin causing further discomfort.

There remains a need for a female incontinence device that can readily conform to female body shape and can provide an effective seal for both mobile and immobile patients whilst remaining comfortable for the patient without intruding into the vagina, anus, meatus or the exterior of the labia majora.. The present invention 5 overcomes these problems by providing a non-intrusive female incontinence device that utilises a flexible strip which has a substantially flat and smooth face in contact with, and forms a seal about, the female external urogenital organs. Accordingly the present invention provides, a female urinary incontinence device comprising a flexible strip having an upper face and a lower face, an opening being provided in the strip 10 communicating between the upper and lower faces, the upper face being substantially flat, a fluid collection means affixed to the lower face of the strip in a fluid tight manner around the opening in the strip and outlet for conveying fluid away from the collection means, the device further comprising means for attaching the device to a support means, wherein the strip and opening are sized and shaped such that when it 15 is stretch fitted over the external urogenital organs the labia minora extends through the opening and a fluid tight fit between the upper face of the strip and the flesh surrounding the base of the labia minora is formed, such that in use urine is conveyed from the urethra, through the labia minora, and into the collection means without leakage.

20 The flexible strip may be constructed of any suitable material having a degree of elasticity and flexibility to maintain a fluid seal during use. Suitable materials include elastomeric materials such as silicone or latex rubbers. Preferably, the material is hypoallergenic.

The opening in the strip is preferably of a substantially oval shape to assist in maintaining a seal about the labia minora. The strip in the region of the opening may also have a substantially oval shape.

- 5      The device further comprises a fluid collection means which surrounds the opening on the lower face of the strip in a fluid tight manner. Preferably, at least the portion of the collection means immediately adjacent the lower face is comprised of the same material as the strip. The collection means, or the portion adjacent the lower face and surrounding the opening, can be affixed to the lower face of the device by for example heat welding or by an adhesive but preferably it is formed integrally with the strip. In  
10     a preferred embodiment, the collection device comprises an oval cup portion surrounding the opening and formed integrally with the strip and of the same material. A second portion of the cup is separated by a thin resilient inner wall also having an opening therein and separating the first portion of the cup from the second portion  
15     which comprises a hard shell narrowing to an outlet toward its lower end which may be attached to a tube for draining urine or other fluid discharge to a storage vessel for subsequent disposal. The interior wall prevents or reduces backflow of discharged fluid, particularly if the user is in a lying position. In a preferred embodiment the collection means comprises a double walled structure, comprising an inner wall open  
20     at its lower end and an outer wall spaced from the inner wall so as to define a cavity between the two walls in which any urine that has not been discharged through the drainage outlet provided in the outer wall is collected and prevented from flowing back into the open end of the inner wall.

The device may be in the form of integral incontinence pants. Attachment means such as Velcro fasteners can be provided to allow for positioning of the device. Preferably the device is in a two part form, the first part comprising the strip and collection means provided with connection means for connection to a support means. The 5 connection means may comprise a plurality of straps that can be connected to straps or tensioning means attached to a waistband. Preferably the connection means between the strap portion and the connections on the support means can be adjusted to maintain a positive tension so as provide a force urging the inner face of the strap against the flesh surrounding the labia minora which helps to maintain a fluid tight seal. The strap portion can for example be connected to the support means by a 10 number of elastic straps.

In a preferred embodiment the flexible strip is bifurcated at the front and rear so as to provide a pair of anterior suspension straps and a pair of posterior suspension straps. The straps are connected to a waistband and can be adjusted to provide an optimum 15 degree of tension so as to maintain an effective seal between flat upper face of the flexible strip and the flesh surrounding the labia minora whilst remaining comfortable for the user.

Preferably the device can be disconnected from the support means so that another can 20 be fitted. The device can then be sterilized for reuse which can provide a considerable cost saving over disposable devices.

The device is comfortable for long term wear, it is non-intrusive in that it does not include any internal support structure such as a vaginal or urethral insertion to hold 25 the device in place and it does not rely on exerting pressure against the exterior of the

labia majora to force the labia majora to provide a seal.. The device does not rely on adhesive or contact sensitive areas such as the vaginal or urethral orifice (meatus). The device can be used for permanently immobilised patients but due to the efficient sealing provided by the flexible elastomeric material the device is also suitable for mobile patients. The device is also much easier for hospital staff to change than devices which require vaginal insertion or catherisation and avoids the possible complications such as infection that can be associated with such procedures. The device can also be used to collect urine from uncooperative patients such as children or those suffering from dementia. The device can also be used to collect other vaginal discharge such as experienced during periods and can be used to collect and measure the amount of bleeding give the doctor an indication of the amount of blood loss.

The invention will now be described by way of example with reference to the accompanying drawings in which:

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Figure 1 is a schematic view of a urinary incontinence device according to an embodiment of the invention.

20 Figure 2 is an exploded schematic view of the major components of the device of the embodiment shown in Fig 1.

Figure 3 is a schematic of a support harness that can be used in conjunction with the device shown in Figures 1 and 2.

25 Figure 4 shows the device of Figure 1 attached to the support harness of Figure 3.

Figure 5 is an exploded schematic view of the device and support harness as worn by a user.

5 Figure 6 shows a device worn by the user and urine collection means.

Referring to Figures 1 and 2, there is shown a urinary incontinence device 13 which comprises a strap part 1 made of a flexible, elastic silicon rubber material, the strap part has a substantially oval central portion 2 having an oval opening 3 therein. A

10 fluid collection part 4 comprises a first cup portion 5 which is formed integrally with the strap part surrounding the opening on the lower face. The first cup portion is about 10mm deep and spaced from the edge of the opening by about 3mm. A second cup part 6 is joined to strip and surrounds the first cup part and is spaced about 10mm from the opening. The second cup part 6 comprises 7 which is formed from the same 15 silicone rubber material as the strip part but is thicker and accordingly more rigid and is spaced from the interior wall so as to define a cavity 24 between the inner and outer walls. The outer cup narrows at its lower end to form a tubular exit 8 that can be connected to drain to an external container. The interior wall 6 is comprised of a resilient and flexible material the same as the strap part but has relatively thin walls 20 which are shaped so as lie against the labia minora or will tend to collapse in on themselves in parts not in contact with the labia minora. An opening 9 is provided which is in communication with the cavity 24. The strap part divides at the front and the rear to provide anterior support straps 11 and posterior support straps 12. The straps are provided with a plurality of attachment points 19 to allow for adjustment of 25 the device.

Referring to Figures 3 and 4, in use the patient is fitted with a support harness 17 comprising a waistband 14 having front support straps 15 and rear support straps 16 attached to the waistband. The front 11 or rear 12 support straps of the incontinence device can be attached by the attachment points 19 to the corresponding front 15 or rear 16 support straps of the harness by the attachment points 20.

Referring to Figures 5 and 6, in use the device stretch fitted so that the labia minora 30 of the patient passes through the opening 3 in the strip portion and through the 10 opening of the interior wall. When the strip portion is relaxed the base of the labia minora is surrounded by the opening in the strip portion. The labia minora lodge in the interior wall 6 of the cup. The anterior and posterior support straps are then engaged with the corresponding support straps on the harness so as to provide sufficient tension to maintain the flat upper surface of the flexible strip against the 15 flesh surrounding the labia minora. Multiple attachment points are provided so that an optimum tension may be achieved for any user and ensure fluid-tight seal is maintained at all times. An effective continuous seal can be maintained from the pubis to beyond the anus. Urine or other fluid exiting through the labia minora passes through the opening 9 of the interior wall and into the cavity 24. The fluid will then 20 drain from the cavity through opening 8 of the exterior wall which is connected via a tube 32 to a collection bag 34. Any fluid not draining through the exit 8 is retained in the cavity 24 and is prevented from draining back through the opening 9 of the inner wall both by the spacing apart of the inner and outer walls and the shaping of the inner wall.